K020345

SEP 6 2002

510(k) Summary

Company: Arthrex, Inc.
Address: 2885 S. Horseshoe Drive, Naples, FL 34104
Phone: (239) 643-5553
Fax: (239) 430-3494

Contact: Vernon C. Brown
Manager of Regulatory Affairs

Trade Name: Arthrex Shoulder Humeral Fracture Prosthesis
Common Name: Shoulder Prosthesis
Classification: Prosthesis, Shoulder, semi-constrained, metal/polymer cemented
Prosthesis, shoulder, Hemi-, Humeral, metallic uncemented

Description:
The device consists of: a stem body with a height adjustment mechanism in the neck section, composed of titanium (Ti6Al4V); a metal head support also of titanium; the prosthesis head composed of Cr-CO alloy. This device may be used for total shoulder repair, utilizing the appropriate Arthrex Univers Glenoid component, which is to be cemented in place.

Intended Use:
The **Arthrex Shoulder Humeral Fracture Prosthesis** is indicated for severe pain or significant disability resulting from degenerative, rheumatoid, or traumatic disease or injury of the glenohumeral joint. This includes traumatic or pathological conditions of the shoulder resulting in fracture of the glenohumeral joint, including impression fractures, comminuted fracture, humeral head fracture, displaced 3-or4-fragment proximal head fractures, avascular necrosis of the humeral head, and fractures of the anatomical neck.

Substantial Equivalence:
By definition, substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and does not raise different questions regarding safety and effectiveness from the predicate device.

The differences between the Arthrex Shoulder Prosthesis and the predicate devices cited do not raise any different questions regarding safety and effectiveness. Furthermore, the materials are well characterized, and have been used in the predicate devices which have nearly identical indications. The device, as designed, is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

Mr. Vernon C. Brown
Manager of Regulatory Affairs
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K020345
Trade/Device Name: Arthrex Shoulder Humeral Fracture Prosthesis
Regulation Number: 21 CFR 888.3660 and 888.3690
Regulation Name: Shoulder joint, metal/polymer, semi-constrained cemented prosthesis; and shoulder joint, humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: KWS and HSD
Dated: May 31, 2002
Received: June 12, 2002

Dear Mr. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 3

Indications for Use Form

510(k) Number (if known): K020345

Device Name: Arthrex Shoulder Humeral Fracture Prosthesis

Indications For Use:

The Arthrex Shoulder Humeral Fracture Prosthesis is indicated for severe pain or significant disability resulting from degenerative, rheumatoid, or traumatic disease or injury of the glenohumeral joint. This includes traumatic or pathological conditions of the shoulder resulting in fracture of the glenohumeral joint, including impression fractures, comminuted fracture, humeral head fracture, displaced 3-or4-fragment proximal head fractures, avascular necrosis of the humeral head, and fractures of the anatomical neck.

The Arthrex Shoulder Humeral Fracture Prosthesis is designed for cemented or non-cemented use. This device may be used for hemi or total shoulder repair, utilizing the appropriate Arthrex Univers Glenoid component, which is to be cemented in place.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020345